December 2018

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601

Happy Holidays!!!!
From the
Kentucky Board of Pharmacy
Board Members and Staff

2019 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2019. The Board will send out a postcard the first week of January 2019 as a reminder (in addition, an email reminder will be sent to all pharmacists with a valid email address on file with the Board). This year the Board encourages you to renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at *www.pharmacy.ky.gov*.**

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually from **January 1 through December 31** pursuant to 201 Kentucky Administrative Regulations (KAR) 2:015 Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2019 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2019. The Board will send out a **postcard** the first week of February 2019 as a reminder (in addition, an email reminder will be sent to all pharmacy technicians with a valid email address on file with the Board). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at *www.pharmacy.ky.gov*.**

2019 CAPTASA Conference

The 2019 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 25-26, 2019, at the Embassy Suites hotel in Lexington, KY. Information on the conference, hotel, and registration can be found at *www.captasa.org*.

Board Soliciting Comments on Hazardous Drug Regulation

At the Board meeting on December 20, 2017, the following pharmacists were appointed to the Hazardous Drug Committee (HDC): Matt Martin, chair, Professional Compounding Centers of America; John Carver, Baptist Health LaGrange Kresge Infusion Pharmacy; Paul Daniels, Board inspector; Jennifer Grove, owner of Bluegrass Drug Center; Chris Harlow, owner of St Matthews Community Pharmacy and past president of Kentucky Pharmacists Association; Barb Jolly, professor at Sullivan University College of Pharmacy; Trenika Mitchell, professor at University of Kentucky College of Pharmacy; and Alyson Roby, owner of Medica Pharmacy and Wellness Center.

The HDC met seven times in 2018 and presented the Board with two options regarding a Kentucky-specific hazardous drug (HD) regulation at the Board meeting on October 17, 2018. The Board is taking comments on the following options until March 31, 2019.

Option One:

1. Incorporate United States Pharmacopeia (USP) General Chapter <800> into a Kentucky Pharmacy Practice Act regulation with changes as outlined below.
2. Delay the implementation date of USP General Chapter <800> to one year from the filing of the Kentucky Pharmacy Practice Act regulation, incorporating USP General Chapter <800> with changes instead of the USP federal implementation date of December 1, 2019.

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National Pharmacy Compliance News

December 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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3. Allow the Board to consider and grant requested waivers from compliance with parts of USP General Chapter <800> if the pharmacy is a low-volume chemotherapy generator. Currently, the Board defines a low-volume chemotherapy generator as a pharmacy that does no more than five compounded sterile chemotherapy preparations in a two-week period (see July 9, 2008 Board meeting minutes).
4. Allow the Board to consider and grant requested waivers to resolve the discrepancies between USP General Chapter <800> and the June 1, 2008 version of USP General Chapter <797>, with which compliance is required per 201 KAR 2:076.
5. Change part of USP General Chapter <800>, Section 2 LIST OF HAZARDOUS DRUGS, Box 1, Containment Requirements, to read (added language in *italics*):

   BOX 1: CONTAINMENT REQUIREMENTS

Drugs on the [National Institute for Occupational Safety and Health (NIOSH)] List that must follow the requirements of this Chapter include: • Any HD [active pharmaceutical ingredient (API)], *except Section 5.3.1* • Any antineoplastic requiring HD manipulation

   USP General Chapter <800> Section 5.3.1 is NONSTERILE COMPOUNDING. It requires manipulation of any HD API, including Table 1, antineoplastic HDs; Table 2, non-antineoplastic HDs; and Table 3, HDs with reproductive effects, to be performed in a containment primary engineering control (C-PEC) such as a biological safety cabinet, compounding aseptic containment isolator, or containment ventilated enclosure and in a containment secondary engineering control (C-SEC) such as a negative pressure, externally vented separated room. This change to Section 2 Box 1 would allow pharmacists to compound with NIOSH List Table 2 and Table 3 APIs and not require the use of a C-PEC or a C-SEC.
6. Change USP General Chapter <800> Section 5.3.1 NONSTERILE COMPOUNDING, paragraph 3, to read (added language in *italics*):

   The C-PEC must be placed in a C-SEC that has at least 12 [Air Changes Per Hour] *for all NIOSH Table 1 APIs. An assessment of risk can be conducted for NIOSH Tables 2 and 3 APIs and manipulated dosage forms.*
7. Change USP General Chapter <800>, Section 15.2 Decontamination, second paragraph, to read (added language in italics):

   The amount of HD contamination introduced into the C-PEC may be reduced by wiping down HD containers. The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs *unless a closed system transfer device (CSTD) is used. When a CSTD is utilized a standard operating procedure (SOP) must be established by the facility to outline the decontamination process during compounding.*

Option Two:

1. Incorporate USP General Chapter <800> into a Kentucky Pharmacy Practice Act regulation.
2. Delay the implementation date of USP General Chapter <800> to one year from the filing of the Kentucky Pharmacy Practice Act regulation, incorporating USP General Chapter <800> instead of the USP Federal implementation date of December 1, 2019.
3. Allow the Board to consider and grant requested waivers from compliance with USP General Chapter <800> to:
   a. Allow pharmacists to perform an assessment of risk to determine the need for a C-SEC for manipulation of any HD dosage form, including APIs on the NIOSH List Table 2, non-antineoplastic HDs; and Table 3, HDs with reproductive effects.
   b. Allow pharmacists to decontaminate the work surface of the C-PEC based on pharmacy SOPs if CSTDs are being used, rather than requiring the work surface to be decontaminated between compounding of different HDs as required by USP General Chapter <800>.
   c. Allow low-volume chemotherapy generating pharmacies to not comply fully with USP General Chapter <800>. Currently, the Board defines a low-volume chemotherapy generator as a pharmacy that generates up to five compounded and sterile chemotherapy preparations in a two-week period (see the July 9, 2008 Board meeting minutes).
   d. Allow resolution between USP General Chapter <800> and the June 1, 2008 version of USP General Chapter <797>, with which compliance is required per 201 KAR 2:076.
   e. Any other reason may be considered.

The deadline for submission of comments is March 31, 2019. Please submit comments by mail, email, or fax to the following:

Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
Frankfort, KY 40601
Email: pharmacy.board@ky.gov
Fax: 502/696-3806

The comments will go to the HDC for review.

Board Meeting Dates 2019 Discussion

At its October 17, 2018 meeting, the Board approved the January 2019 meeting to be held on January 30, 2019, at the Board office in Frankfort, KY, starting at 9 AM. The Board will decide the remaining 2019 meeting dates and locations at its December 12, 2018 meeting to be held at the Board office in Frankfort, starting at 9 AM.

The Board is considering moving from seven meetings a year to monthly meetings. However, this decision will be made on December 12, 2018. Once the meeting dates and locations are set, the information will be available on the Board's website, *www.pharmacy.ky.gov,* under the Calendar section of Board Information.

Cheryl Lalonde Retires From State Government

Cheryl Lalonde, general counsel, retired from the Board on November 30, 2018. Cheryl served as an assistant attorney general from 1996 until her employment as the Board's first in-house general counsel on November 1, 2015. The Board appreciates her dedication and wishes her well in her retirement.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically, in a folder, or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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